

REMARKS

Reconsideration of the pending application is respectfully requested on the basis of the following particulars.

1. Election

The applicant acknowledges the election without traverse of Group I, claims 1 and 3-16, and the withdrawal of claims 17-30 from further consideration.

2. Information disclosure statement

The applicant respectfully requests in the next Office communication consideration of, and return of a signed copy of the Form PTO/SB/08A filed on August 17, 2007.

3. In the claims

As shown in the foregoing AMENDMENT TO THE CLAIMS, the claims have been amended to more clearly point out the subject matter for which protection is sought.

A. Claim amendments

Claim 1 is amended to provide clear antecedent basis for every claim element and to provide clarity. It is respectfully submitted that no new matter is added as the changes merely correct minor informalities.

Claim 2 remains canceled.

Claim 3 is amended to correct minor informalities and to remove the exemplary language "or the like." It is respectfully submitted that no new matter is added as the changes merely correct minor informalities.

Claim 4 is amended to provide clarity. It is respectfully submitted that no new matter is added as the changes merely correct minor informalities.

Claim 9 is amended for consistent antecedent basis with amended claim 1. It is respectfully submitted that no new matter is added as the changes merely correct minor informalities.

Claim 11 is amended for consistent antecedent basis with amended claim 1. It is respectfully submitted that no new matter is added as the changes merely correct minor informalities.

Claim 12 is amended for consistent antecedent basis with amended claim 1. It is respectfully submitted that no new matter is added as the changes merely correct minor informalities.

Claim 13 is amended for consistent antecedent basis with amended claim 1. It is respectfully submitted that no new matter is added as the changes merely correct minor informalities.

Claim 16 is amended to correct a minor informality. It is respectfully submitted that no new matter is added as the changes merely correct minor informalities.

Claims 5-8, 10, 14, and 15 are left unchanged.

Claims 17-30 are withdrawn from further consideration.

Entry of the AMENDMENT TO THE CLAIMS is respectfully requested in the next Office communication.

B. Rejection of claim 3 under 35 U.S.C. § 112 second paragraph

Reconsideration and withdrawal of this rejection is respectfully requested, in view of the amendment to claim 3 above, on the basis that amended claim 3 is clear and definite.

The exemplary language “or the like,” as discussed above, has been removed from claim 3. Accordingly, amended claim 3 is clear and definite and withdrawal of this rejection is respectfully requested.

4. Rejection of claims 1 and 3-5 under 35 U.S.C. § 102(b) as being anticipated by WO 01/70311 (*Chiba*), in view of the translation of related document JP 2001-259031

Reconsideration of this rejection is respectfully requested on the basis that the *Chiba* publication fails to disclose each and every recited step or element of pending claim 1. Claims 3-5 depend from claim 1, and are therefore patentable as containing all of the recited steps and elements of claim 1, as well as for their respective recited features.

In review, the embodiment of pending claim 1 requires a method of manufacturing a plunger for a medical syringe, the plunger having a piston body provided at a front end of a longitudinal plunger body. The piston body is formed from a plastic which is softer than the plastic used to form the plunger body. The plunger, or at least part of the plunger, is formed by first manufacturing the piston body and then the plunger body. This is accomplished by injection molding, wherein the plunger body or a part of the plunger body is injected against the piston body. The piston body includes a front side and a side wall, and is formed such that the front side and sidewall are free of any flash lines and/or gate points for the plastic.

The *Chiba* publication fails to disclose all of the steps and elements recited in pending claim 1. In particular, the *Chiba* publication fails to disclose first forming the piston body and next forming the plunger body. Further, the *Chiba* publication fails to disclose the piston body having a front side and a sidewall free of any flash lines and/or gate points for the plastic.

As is clearly discussed in the *Chiba* publication the plunger portion 5 is manufactured first (paragraph [0015]). Next, the plunger 5 is placed in the mold 21a, 21b and then the gasket 6 is formed (paragraph [0016]). Accordingly, the *Chiba* publication fails to disclose first forming the piston body and next forming the plunger body, as is required by pending claim 1.

Additionally, as can clearly be seen in Figs. 2(a)-(c) of the *Chiba* publication, the front side and the sidewalls of the gasket 6 include a gate point for the plastic and

flash lines, respectively, contrary to the requirement of pending claim 1, which requires the front side and sidewalls to be free of flash lines and/or gate points.

For clarification, the flash lines are formed on the side wall of the gasket 6 along the split between the molds 21a, 21b. This is due to the fact that some of the thermoplastic elastomer material injected to form the gasket 6 will fill in the gaps defined by the split, no matter how small the gaps are.

Further, the gate point is clearly identified at the front side of the gasket 6 as a pin point gate 23 (Figs. 2(a)-(c); paragraph [0015]).

Thus, the *Chiba* publication fails to disclose all of the steps and elements recited in pending claim 1. In particular, the *Chiba* publication fails to disclose first forming the piston body and next forming the plunger body. Further, the *Chiba* publication fails to disclose the piston body having a front side and a sidewall free of any flash lines and/or gate points for the plastic. Accordingly, withdrawal of this rejection is respectfully requested.

As mentioned above, applicants submit that independent claim 1 is patentable and therefore, claims 3-5, which depend from claim 1, are also considered to be patentable as containing all of the steps and elements of claim 1, as well as for their respective recited features.

Further, with respect to claim 4, the *Chiba* publication fails to disclose the piston body having at least one inwardly directed part and corresponding lateral recesses in a protruding part of a mold part. Instead, the *Chiba* publication discloses, if anything, a protruding part on the plunger. There are no corresponding lateral recesses formed in a protruding part of a mold part in the *Chiba* publication, as required by pending claim 4. Accordingly, withdrawal of this rejection is respectfully requested.

Further still, with respect to claim 5, the *Chiba* publication fails to disclose providing the plastic for forming the piston body from a back side of the piston body. Instead, the *Chiba* publication clearly discloses providing the plastic for forming the

gasket 6 from a front side of the gasket 6 (Figs. 2(a)-(c); paragraph [0015]). Accordingly, withdrawal of this rejection is respectfully requested.

5. Rejection of claim 16 under 35 U.S.C. § 102(b) as being anticipated by U.S. patent no. 5,782,803 (*Jentzen*)

Reconsideration of this rejection is respectfully requested on the basis that the *Jentzen* patent fails to disclose each and every recited step or element of pending claim 16.

By way of review, the embodiment of pending claim 16 requires that the piston body be formed with a piston body part extending from a front side of the piston body, and the piston body part being formed of a material which is different from the piston body.

In contrast, the *Jentzen* patent discloses a sealing element 300, corresponding to a piston body, with a unitary extending nose tip 301. These elements are both formed from the same elastomeric material, in contrast to the requirement of pending claim 16 that the piston body part is formed of a material which is different from the piston body.

Accordingly, the *Jentzen* patent fails to disclose each and every recited step or element of pending claim 16, and withdrawal of this rejection is respectfully requested.

6. Rejection of claims 6 and 7 under 35 U.S.C. § 103(a) as being unpatentable over WO 01/70311 (*Chiba*) in view of U.S. patent no. 5,030,406 (*Sorensen*)

Reconsideration of this rejection is respectfully requested on the basis that the rejection fails to establish a *prima facie* case of obviousness with respect to claims 6 and 7.

As discussed above, the *Chiba* publication fails to disclose every step and element of pending claim 1, from which claims 6 and 7 depend.

The *Sorensen* patent fails to provide for the shortcomings of the *Chiba* publication discussed above. In particular, the *Sorensen* patent fails to disclose first forming a piston body and next forming a plunger body and further, fails to disclose a piston body having a front side and a sidewall free of any flash lines and/or gate points, all as required by pending claim 1.

Thus, the proposed combination of the *Chiba* publication and the *Sorensen* patent inherently fails to disclose every feature of pending claim 1, from which claims 6 and 7 depend, since neither the *Chiba* publication nor the *Sorensen* patent disclose first forming a piston body and next forming a plunger body and further, a piston body having a front side and a sidewall free of any flash lines and/or gate points.

Accordingly, since the proposed combination fails to disclose every feature of pending claim 1, from which claims 6 and 7 depend, a *prima facie* case of obviousness cannot be maintained, and withdrawal of this rejection is respectfully requested.

7. Rejection of claims 8 under 35 U.S.C. § 103(a) as being unpatentable over WO 01/70311 (*Chiba*)

Reconsideration of this rejection is respectfully requested on the basis that the rejection fails to establish a *prima facie* case of obviousness with respect to claim 8.

As discussed above, the *Chiba* publication fails to disclose every step and element of pending claim 1, from which claim 8 depends. Further, the assertion that it would have been obvious to a skilled artisan to form the gasket of the *Chiba* publication first and then form the plunger body lacks merit, since, as can be clearly seen in Figs 2(a)-(c), the *Chiba* publication discloses using the completely formed plunger body to provide at least one wall of the molding chamber for the gasket 6.

Thus, if the gasket were to be formed first, without the plunger body in place, the gasket material would simply fill in the entire mold cavity where the completed plunger body should be positioned. Thus, the gasket would take the form of the

gasket and the plunger body. Of course, a skilled artisan would recognize this as an unsuitable manner for forming a two piece plunger body and piston body.

Accordingly, since the *Chiba* publication fails to disclose every step and element of pending claim 1, and since a skilled artisan would not have had any suggestion to switch the order of forming the gasket and plunger body, a *prima facie* case of obviousness cannot be maintained, and withdrawal of this rejection is respectfully requested.

8. Rejection of claims 9-13 under 35 U.S.C. § 103(a) as being unpatentable over WO 01/70311 (*Chiba*) in view of U.S. patent no. 3,659,749 (*Schwartz*)

Reconsideration of this rejection is respectfully requested on the basis that the rejection fails to establish a *prima facie* case of obviousness with respect to claims 9-13.

As discussed above, the *Chiba* publication fails to disclose every step and element of pending claim 1, from which claims 9-13 depend.

The *Schwartz* patent fails to provide for the shortcomings of the *Chiba* publication discussed above. In particular, the *Schwartz* patent fails to disclose first forming a piston body and next forming a plunger body and further, fails to disclose a piston body having a front side and a sidewall free of any flash lines and/or gate points, all as required by pending claim 1.

Thus, the proposed combination of the *Chiba* publication and the *Schwartz* patent inherently fails to disclose every feature of pending claim 1, from which claims 6 and 7 depend, since neither the *Chiba* publication nor the *Schwartz* patent disclose first forming a piston body and next forming a plunger body and further, a piston body having a front side and a sidewall free of any flash lines and/or gate points.

Further, with respect to claim 9, the accessory element 42 of the *Schwartz* patent is disclosed as being formed at the front side of the plunger body, and not at the front side of the piston body. The Office action acknowledges on page 5 that the *Chiba* publication fails to disclose an accessory element.

Thus, the proposed combination of the *Chiba* publication and the *Schwartz* patent inherently fails to disclose every feature of pending claim 9, from which claims 10-13 depend, since neither the *Chiba* publication nor the *Schwartz* patent disclose an accessory element formed or located with at least a part thereof on the front side of the piston body.

Accordingly, since the proposed combination fails to disclose every feature of pending claim 1, from which claims 9-13 depend, a *prima facie* case of obviousness cannot be maintained, and withdrawal of this rejection is respectfully requested.

9. Rejection of claims 14 and 15 under 35 U.S.C. § 103(a) as being unpatentable over WO 01/70311 (*Chiba*) in view of U.S. patent no. 4,861,335 (*Reynolds*)

Reconsideration of this rejection is respectfully requested on the basis that the rejection fails to establish a *prima facie* case of obviousness with respect to claims 14 and 15.

As discussed above, the *Chiba* publication fails to disclose every step and element of pending claim 1, from which claims 14 and 15 depend.

The *Reynolds* patent fails to provide for the shortcomings of the *Chiba* publication discussed above. In particular, the *Reynolds* patent fails to disclose first forming a piston body and next forming a plunger body and further, fails to disclose a piston body having a front side and a sidewall free of any flash lines and/or gate points, all as required by pending claim 1.

Thus, the proposed combination of the *Chiba* publication and the *Reynolds* patent inherently fails to disclose every feature of pending claim 1, from which claims 6 and 7 depend, since neither the *Chiba* publication nor the *Reynolds* patent disclose first forming a piston body and next forming a plunger body and further, a piston body having a front side and a sidewall free of any flash lines and/or gate points.

Further, with respect to claim 14, the method still requires a part of the plunger body to be injected against the piston body. This feature is simply not disclosed in either the *Chiba* publication or the *Reynolds* patent.



Additionally with respect to claim 15, the plug 12 of the *Reynolds* patent is not equivalent to a drive element, which would itself drive the plunger body within the housing of the cylinder. Thus, the *Reynolds* patent fails to disclose a drive element. The Office action acknowledges on page 6 that the *Chiba* publication fails to disclose a drive element.

Thus, the proposed combination of the *Chiba* publication and the *Reynolds* patent inherently fails to disclose every feature of pending claims 14 and 15, since neither the *Chiba* publication nor the *Reynolds* patent disclose injecting a part of the plunger body against the piston body and the use of a drive element.

Accordingly, since the proposed combination fails to disclose every feature of pending claim 1, from which claims 14 and 15 depend, a *prima facie* case of obviousness cannot be maintained, and withdrawal of this rejection is respectfully requested.

10. Conclusion

As a result of the amendment to the claims, and further in view of the foregoing remarks, it is respectfully submitted that the application is in condition for allowance. Accordingly, it is respectfully requested that every pending claim in the present application be allowed and the application be passed to issue.

If any issues remain that may be resolved by a telephone or facsimile communication with the applicant's attorney, the examiner is invited to contact the undersigned at the numbers shown below.

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Respectfully submitted,

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